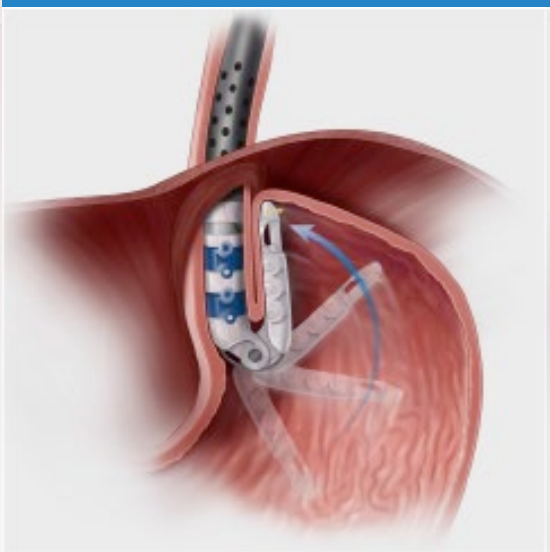
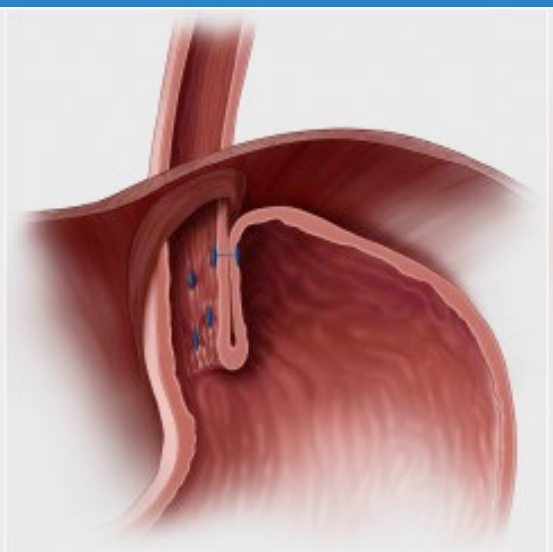
TIF® Procedure
FOR REFLUX

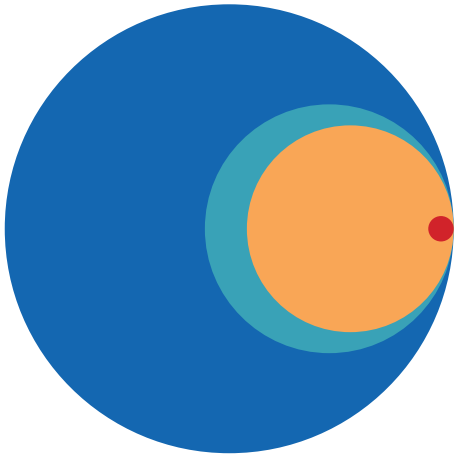




EndoGastric Solutions®

TIF® Procedure for Reflux

Gastroesophageal Reflux Disease (GERD)[1,2]

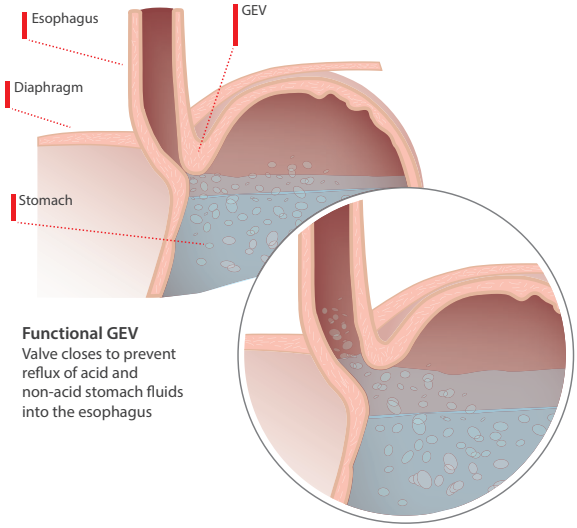


81 Million Americans suffer with symptoms

10 million see a doctor

6.7 million receive a diagnosis

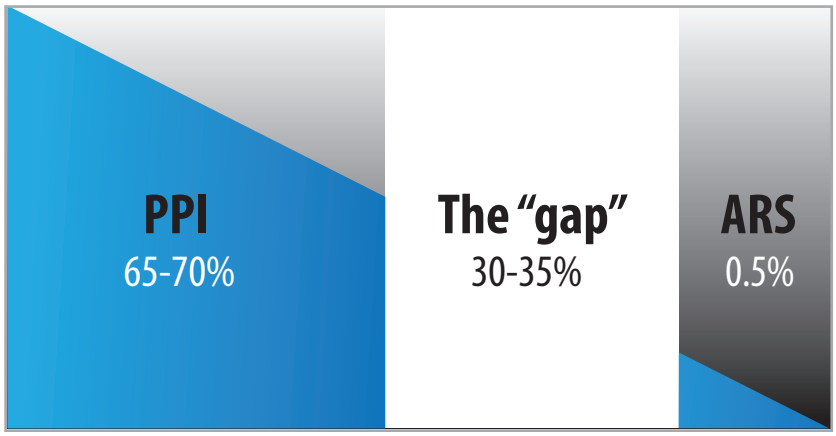
Only 30,000 choose traditional surgery as treatment



Functional GEV
Valve closes to prevent reflux of acid and non-acid stomach fluids into the esophagus

Dysfunctional GEV
Valve is unable to close, allowing stomach fluids to reflux into esophagus

Most patients treat their GERD with OTC or Rx medications—most frequently proton pump inhibitors (PPIs). For some patients, these medications don't adequately control symptoms or may stop working after extended use. These patients are considered refractory to PPIs. Other patients are uncomfortable with side-effects and long-term dependence. Patients are increasingly uncomfortable with traditional anti-reflux surgery (ARS). The treatment gap for GERD patients refractory to PPIs is significant. Patients are interested in a procedure that improves symptom control and reduces medication dependence.[3]



Transoral Incisionless Fundoplication - the TIF procedure, fills the refractory GERD treatment gap. Using an endoscopic approach - similar to diagnostic EGD - the gastroesophageal valve (GEV) is reconstructed without incisions following principles of traditional fundoplication (see cover illustrations).

The TIF procedure maintains an exemplary safety profile with minimal side-effects. Clinical studies report a less than 3% occurrence of gas bloat and dysphagia. Clinical studies evaluating feasibility, safety and initial learning curve have reported a serious adverse event (SAE) rate of <3%. The commercial SAE rate in more than 17,000 procedures is very low <0.45% (1 in every 250 cases).[4]

LOTUS RCT 5-yr[5]	PPI	ARS
Serious Adverse Events (SAE)	24.1%	28.6%
Dysphagia	11%	5%
Gas Bloat	28%	40%
Flatulance	40%	57%

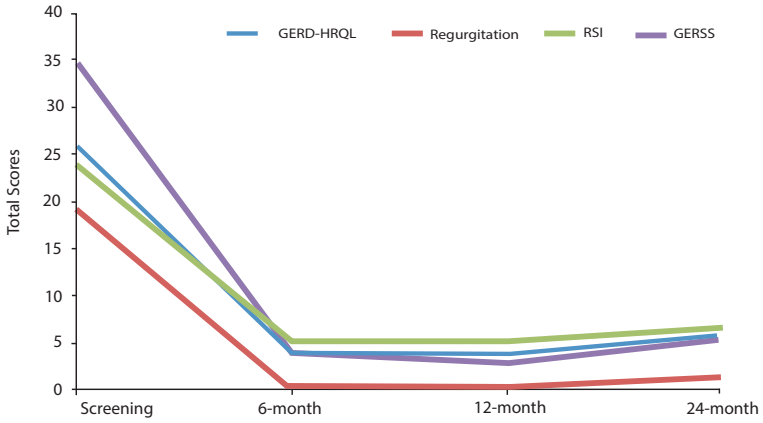
Data Supports GERD Treatment Gap Option

2 Years TIF Procedure Durability

In the US TIF Registry study, at two year follow-up: [6]

- All symptom scores improved significantly from before TIF procedure and didn't change significantly between 6, 12, 24 month follow-up as measured by validated questionnaires
- US Registry data; n = 127

GERD-HRQL = Health Related Quality of Life
Regurgitation = Reflux Disease Questionnaire
RSI = Reflux Symptom Index
GERSS = GastroEsophageal Reflux Symptom Score

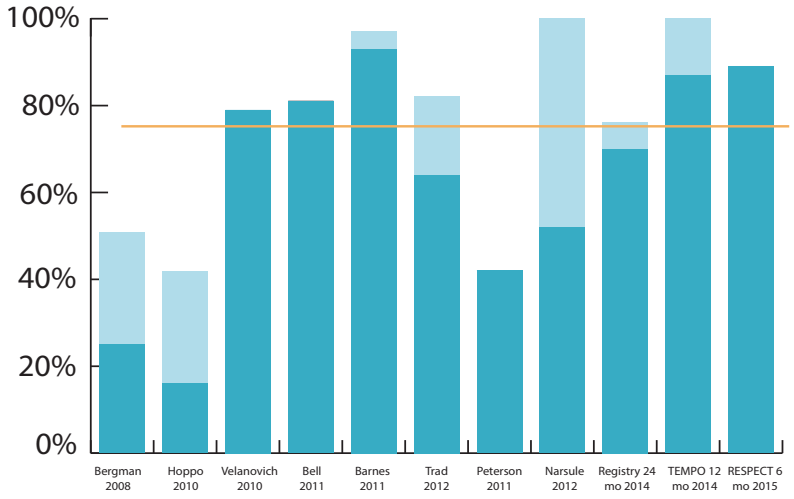


All symptoms scores improved significantly from before TIF procedure, and did not change significantly between 6, 12 and 24 month follow-up.

75% of TIF Patients Off PPIs [6-16]

- Weighted average % of patients completely off PPIs
- 75% completely off PPIs; 10% occasional use
- 11 studies; n=520 patients (weighted average follow-up at 10 mos.)

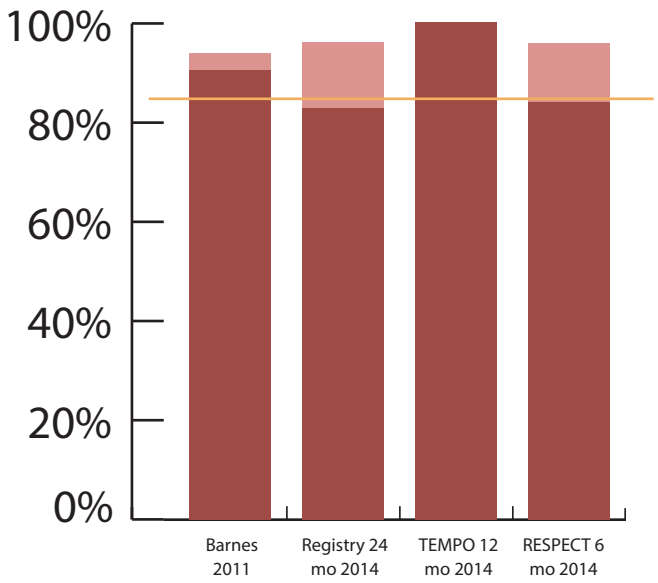
Post-TIF PPI Use (Completetly Off)
Post-TIF PPI Use (Occasional)

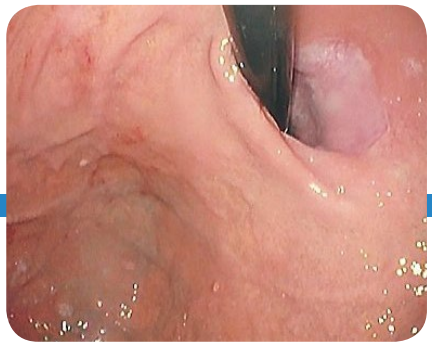


85% of TIF Patients' Esophagitis Healed [6,11,15,16]

- Weighted average % of patients esophagitis completely healed
- 85% completely healed; 6% improved
- 4 studies; n=79 patients (weighted average follow-up at 9 mos.)

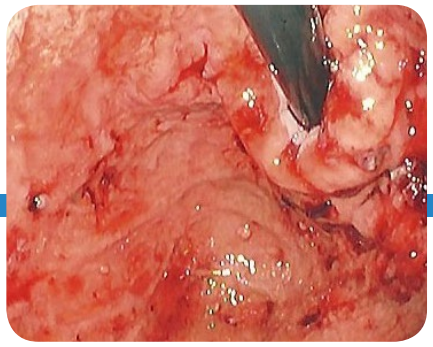
Completely Healed
Improved 1 Grade





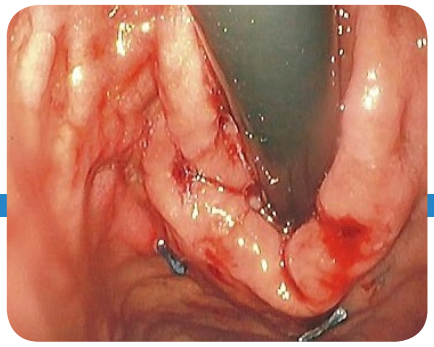
Pre-procedure esophagogastro-duodenoscopy (EGD)

Note: The gastroesophageal junction (GEJ) is displaced; valve and anti-reflux barrier are deteriorated. GEV is loosely adherent to the scope and appears incompetent. Phrenoesophageal membrane lengthens, allowing displacement of the GEJ. Small hiatal hernia present.



EGD after completion of TIF procedure

Note: A 270° fundoplication with a 3cm length valve was created. Small hiatal hernia was reduced. GEV is tight to the endoscope and competent. The intra-abdominal esophageal segment is elongated. The dynamics of angle of His have been restored.



The **TIF procedure** follows well established principles of anti-reflux surgery described in SAGES Guidelines [17]

"This patient reports symptoms are completely controlled and remains off PPIs over ***TWO YEARS*** *after their TIF procedure."*

- Peter Janu, M.D., Chilton, WI

17,000+	800+	50+	4	Cat 1
procedures worldwide since EsophyX® device clearance in 2007	unique patients studied in 40+ centers with consistent outcomes	peer-reviewed clinical papers in respected gastroenterology and surgical journals	published randomized controlled trials including two with TIF/placebo vs. sham/PPI controlled arms	CPT® Code Esophagogastric Fundoplasty Trans-Orifice procedures effective 1/1/2016

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www.gerdhelp.com/blog/references/references-tif-procedure-brochure/

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